

Atty. Docket No.: PF3623USw  
S/N 09/936,506

REMARKS

The Examiner has objected to the specification as including embedded hyperlinks and/or browser-executable code. The applicants have amended the specification at pages 5 and 26, deleting the hyperlinks/executable code.

The Examiner has rejected claims 9-17 and 27 under 35 U.S.C. 102(b) as being anticipated by Hunt et al. (P.N.A.S. 82 5455-6459, 1985) and as being anticipated by Bromley et al. (WO87/00861). Applicants have cancelled claims 9-17 and 27.

The Examiner has rejected claims 28-31 under 35 U.S.C. 112 first paragraph as failing to comply with the enablement requirement. The Examiner states that the claims are broad and encompass unpredictable gene therapy techniques. The Examiner argues that because gene therapy is unpredictable, the applicants cannot rely upon the disclosure in the specification and the prior art to satisfy the enablement requirement.

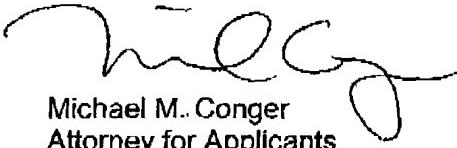
Applicants have amended the claims by canceling claim 28 and traverse in part the Examiner's rejection. The Examiner has cited considerable evidence of the unpredictable nature of gene therapy. However, the difficulties relating to gene therapy techniques cited by the Examiner are not relevant to the claims as presently amended. Since the claims as amended are drawn to use of the molecule in DNA vaccination, and not to the unpredictable gene therapy techniques cited by the Examiner, the disclosure provided by the specification and the prior art are sufficient to allow one skilled in the art to practice the invention as set forth in the amended claims without undue experimentation. In light of the amendment, applicants request the rejection be withdrawn.

Atty. Docket No.: PF3623USW  
S/N 09/936,506

Claims 1-17 and claims 27-31 have been rejected under 35 U.S.C. 112 as being indefinite. The Examiner states that the claims fail to recite the location of the DNA molecule with respect to the encoding region. Applicants have amended claim 1 to indicate the molecule is operably linked to the 5' end of the region. Claim 27 is rejected under 35 U.S.C. 112 as being indefinite and under 35 U.S.C. 101 as not being a proper process claim. Claim 27 has been canceled.

Applicants submit that the claims are in condition for allowance and request favorable reconsideration. If the Examiner has any questions or concerns, the Examiner is invited to contact the undersigned.

Respectfully submitted,



Michael M. Conger  
Attorney for Applicants  
Registration No. 43,562

Date: July 12, 2004  
GlaxoSmithKline  
Five Moore Drive, PO Box 13398  
Research Triangle Park  
North Carolina 27709  
Telephone: (919)483-2474  
Facsimile: (919)483-7988

Atty. Docket No.: PF3623USw  
S/N 09/936,506

Marked Version Showing Changes

Page 5

For the purposes of the present invention  $\Delta G$  can be calculated using the RNA structural prediction program MFOLD ( Zuker M. and Jacobson A.B. (1995) Nucleic Ac. Res. (23) 2791-2798). Predicted  $\Delta G$  values may be calculated using the program located at the internet: <http://mfold1.wustl.edu/mfold/mRNA/form1.cgi>

Atty. Docket No.: PF3623USw  
S/N 09/936,506

Marked Version Showing Changes

Page 26

**"Sequence identity"**

For the purposes of the present invention, sequence identity may be determined, for example, by using the ALIGN program (version 2.0). This calculates a global alignment of two sequences. (See Myers and Miller,(1989) CABIOS, 4, 11-17).

Gap penalties: -16/-4. For information see

<http://www.infobiogen.fr/services/menuserv.html>